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Attn: Barbara A. Wrigley
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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3769

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New section (e) of claim 3 recites in lines 2-4 “having a width that is confined by two to four of the needles.” Applicant states figure 3 provides support for this recitation. This interpretation by Applicant is incorrect, as the needle array shown in figure 3 does in no way confine the heat-treated tissue volume. The issue of “confinement” versus “radiation power profile/distribution” was noted in the office actions of the parent applicant 09/762,285, now US Patent 6,625,990.

In order to provide an examination, the examiner interprets the above recitation as “two to four needles define a width of the heat-treated tissue volume.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 12-19 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (5,472,441) in view of Edwards (5,836,906) in still further view of Swanson (6,267,760) and still in further view of Daniel et al. (7,008,421).

Regarding claims 1-6, 12-14, 19 Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. It should be noted the mere application of electromagnetic energy to the tissue by the needle array creates a heat-treated

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tissue volume (having a desired length, width and depth). Edwards et al. clearly disclose at least two needles which define a radiation pattern having a localized power profile/distribution centered on the needles, which is interpreted as confining the heat-treated tissue volume (which coincides with the power profile/distribution), see 1110 of figure 11. Additionally, having the heat-treated tissue volume center coincide with the planned incision line is extremely well known and desirable, as the heat-treated tissue volume center/line of center is the point/line of maximum symmetry and therefore the best location to place the incision. Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. fail to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Finally, Edwards et al. fail to explicitly disclose bloodless resection of tissue. Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Edwards discloses a tissue heating device having retractable needles (12) and teaches an alternative or equivalent energy delivery of microwave with cooling means and RF, see col. 1-7 and particularly col. 7, lines 28-38 and figures 1-6. Swanson

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discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. Daniel et al. disclose a device very similar to that of Edwards I and teach the method of heating the tissue sufficiently with the needles in order to bloodlessly resect tissue, see abstract, col. 2, line 63 through col. 3, line 65, col. 4-6. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., as taught by Edwards, to use microwave (electromagnetic) energy as an alternate means of heating tissue, and as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, and as taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue, and as is also well known to place the incision line at the center/line of center of the heat-treated tissue volume since that is the point/line of maximum heat-treated tissue volume symmetry and as finally taught by Daniel et al., to heat the tissue sufficiently with the needles in order to resect the tissue bloodlessly.

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Regarding claims 15-18, 28-31 and 33-35, Edwards et al. in view of Swanson and further in view of Daniel et al. disclose the claimed invention, see Edwards et al. col. 6-14 and figure 16.

Regarding claims 25-27, Edwards et al. in view of Swanson and further in view of Daniel et al. disclose the claimed invention, see Edwards et al. figures 1-16.

Regarding claim 32, Edwards et al. in view of Swanson and further in view of Daniel et al. disclose the claimed invention, see the conducting wires connected to the needles of (Edwards I) in figures 1-16.

Claims 7-11 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (5,472,441) in view of Edwards (5,836,906) in still further view of Swanson (6,267,760) and still in further view of Daniel et al. (7,008,421) as applied to claims 1, 3 and 6 above, and still further in view of admitted prior art.

Regarding claims 7-11 and 20-24 Edwards et al. in view of Swanson and further in view of Daniel et al. disclose the claimed invention in further view of Applicant's admission on the record that the claimed species are not patentably distinct as noted above.

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Claims 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (5,472,441) in view of Swanson (6,267,760) and further in view of Daniel et al. (7,008,421).

Regarding claims 37 and 40, Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. It should be noted the mere application of electromagnetic energy to the tissue by the needle array creates a heat-treated tissue volume (having a desired length, width and depth). Edwards et al. clearly

disclose at least two needles which define a radiation pattern having a localized power profile/distribution centered on the needles, which is interpreted as confining/defining the heat-treated tissue volume (which coincides with the power profile/distribution), see 1110 of figure 11. Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. fail to disclose to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Finally, Edwards et al. fail to explicitly disclose bloodless resection of tissue. Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. Additionally, having the heat-treated tissue volume and/or width straddle the planned incision line is inherent, as Swanson teaches incising within the heat-treated volume. Daniel et al. disclose a device very similar to that of Edwards I and teach the method of heating the tissue sufficiently with the needles in order to bloodlessly resect tissue, see abstract,

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col. 2, line 63 through col. 3, line 65, col. 4-6. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, as taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue, and as is also well known to place the incision line at the center/line of center of the heat-treated tissue volume since that is the point/line of maximum heat-treated tissue volume symmetry and as finally taught by Daniel et al., to heat the tissue sufficiently with the needles in order to resect the tissue bloodlessly.

Regarding claim 38, Edwards et al. in view of Swanson and further in view of Daniel et al. disclose the claimed invention as the tissue heat-treating device makes an ablation lesion locally and the device must be removed so that the lesion area is free to be incised.

Regarding claim 39, Edwards et al. in view of Swanson and further in view of Daniel et al. disclose the claimed invention, see Swanson col. 8:33-41, col. 45:19-43.

Regarding claim 41, Edwards et al. disclose the claimed invention see figure 11.

Regarding claim 42, Edwards et al. disclose the claimed invention, see col. 3:11-28.

Regarding claims 43 and 44, Edwards et al. disclose the claimed invention, see col. 3 and figures 1-19.

Response to Arguments

Applicant's arguments filed 7/17/2008 with respect to claims 1-6, 12-19 and 25-36 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

On page 2 of 12, 2nd to last paragraph (last full paragraph), Applicant asserts "Daniel et al. is not prior art to the present application Applicant respectfully suggests that the combination of Edwards '441, Edwards '906 and Swanson '706 suggested by the Examiner does not teach, suggest or disclose the claimed invention. Allowance is respectfully requested." The examiner disagrees. The Daniel et al. patent is used to teach the "bloodless resection of tissue. Applicants disclose the bloodless resection of tissue only in the present Application and not in any of the earlier filed priority documents. Therefore, Applicant is entitled to a priority date of 7/22/2003 in regards to the bloodless resection of tissue, not the earlier filing date of 8/4/1998 which is a valid priority date for most of the other recited subject matter.

With regards to arguments/remarks against the rejection of claim 3, last three lines on page 2 of 12 through first three lines on page 3 of 12, this argument/remark is moot due to the new grounds of rejection. Since the volume of heat-treated tissue is symmetric, since the grid needle arrangement is symmetric, an incision placed at the center is least likely of all incision positions to bleed as that is the position/line of highest temperature, radiation and absorption of radiation/power within the tissue. It would be obvious to one of ordinary skill in the art to place the incision there for the above noted rationale.

With regard to arguments/remarks against the rejections of claims 37 to 44, the recited tissue volume that straddles the incision line is inherently met by the prior art as any incision made in the heat-treated tissue volume (an incision which the prior art clearly discloses) is straddled and/or equivalently surrounded on both sides by the heat-treated tissue volume.

Next, on page 4 of 12, first paragraph, regarding the Shevchenko and Bismuth declarations, Applicant states "the Examiner states that the claims are directed to a method of use and the support offered by the declaration is the estimated market share of a device not the method of use. Applicant respectfully suggest that it has fully complied with the requirements of MPEP §716.03(a) as the evidence of commercial success offered is indeed commensurate in scope with the claims. The Applicant has offered evidence of the relationship between the claimed features, the commercial product and the process of using the product. The apparatus creates the method of use. There is no method of using the product without the product itself. Therefore, evidence

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of the commercial success of the product is indeed relevant to the process. Applicant respectfully requests reconsideration of the Shevchenko Declaration." The point(s) of contention presently here in this application (as viewed by the examiner) is/are the various method steps and not only or essentially the device which both the declarations are directed to. In point of fact, the insufficiency of the declarations is because "the showing is not commensurate with the scope of the claims." The present claims are directed to the method of using a particular device in a particular fashion, since the declarations do not address or adequately address the disclosed method, the examiner believes the above insufficiency statement to be appropriate.

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art
Unit 3769